Amendments to the Drawings:

Please replace sheet(s) 1 of the drawings with the attached replacement sheet(s) 1. The replacement sheet(s) incorporate the desired changes in the drawings, and each sheet includes all of the figures that appeared on the immediately prior version of that sheet.

Attachment: Replacement Sheet 1

REMARKS

The above amendments and these remarks are responsive to the final Office action dated April 20, 2007. Claims 1–11, 13–20, 23, and 27–31 are pending in the application. Claims 1–11, 13–17, 23, and 29 are rejected. Claims 18–20, 27–28 and 30–31 have been withdrawn from consideration as being drawn to a nonelected species. By way of the present amendment, claims 1 and 11, the drawings, and the specification have been amended. In view of the amendments above, and the remarks below, applicant respectfully requests reconsideration of the application under 37 C.F.R. § 1.111 and allowance of the pending claims.

As an initial matter, applicant thanks the Examiner for her time during a telephone interview on May 24, 2007. During the interview, the following subjects were discussed: the effective dates of Hauschild et al. (U.S. Pat. No. 6,905,475) and the claimed subject matter, the support in the specification for the claimed pressure range between about 643 psig and about 2001 psig, the withdrawal from consideration of certain claims, and the need to file an RCE. During the interview, the Examiner agreed that the as-filed specification provided support for the claimed numerical pressure ranges, and the Examiner stated that, absent amendments to the claims, she would likely not require extra searching to consider arguments regarding the effective dates of Hauschild et al. and the claimed subject matter or the withdrawal from consideration of certain claims.

Election/Restrictions

As noted above, in the Office action, the Examiner has withdrawn claims 18–20, 27–28 and 30–31 as being drawn to a nonelected species. The Examiner asserts that claims 18–20, 27–28 and 30–31 are drawn to species (G). Accordingly, the Examiner has withdrawn these claims as being "no longer directed towards species C."

Applicant initially notes that species (C) (injector may include an injection chamber) was elected with traverse pursuant to an earlier species election requirement. However, although claims 18–20, 27–28 and 30–31 are drawn to species (G) (where the distal region 22 is angled relative to rest of effector), the features recited in these claims are in no way inconsistent with species (C), or, for that matter, with any of the other identified species. In particular, these claims neither require nor exclude: (A) an injector with a cap; (B) an injector with a valve; (C) an injector with an injection chamber; (D) that the reservoir be housed within the injector body; (E) a separate fluid reservoir; (F) a motor driven stop; or (H) that the end effector measures between four and ten inches. Thus, claims 18–20, 27–28 and 30–31 remain drawn to all of species (A) through (H). Thus, applicant asserts that these claims, although drawn to species (G), remain generic to and link the identified species (A) through (F) and (H). Accordingly, claims 18–20, 27–28 and 30–31 should be considered with the elected species. Applicant therefore respectfully requests that the Examiner withdraw the finality of the Office action dated April 20, 2007, and consider claims 18–20, 27–28 and 30–31.

If the Examiner considers claims 18–20, 27–28 and 30–31, applicant respectfully asserts that claims 18–20, 27–28 and 30–31 are allowable for at least the reasons discussed with respect to such claims in the amendment filed January 19, 2007.

Additionally, applicant notes that claims 1–11, 13–17, 23, and 29 remain drawn to species (A) through (F) and (H), and are generic to and link such species. In particular, these claims neither require nor exclude: (A) an injector with a cap; (B) an injector with a valve; (C) an injector with an injection chamber; (D) that the reservoir be housed within the injector body; (E) a separate fluid reservoir; (F) a motor driven stop; or (H) that the end effector measures between four and ten inches.

Objections to the Drawings

The Examiner has objected to the drawings under 37 C.F.R. § 1.83(a). In particular, the Examiner has requested that the element of a "plunger powered by a gas cartridge" in claim 11 be shown in the drawings. Applicant has amended sheet 1 of the drawings to show such features. Accordingly, applicant respectfully requests that the objection to the drawings be withdrawn. In addition, applicant has amended the paragraph beginning at page 6, line 3 of the specification to reflect these changes.

Objection to the Specification and Rejections under 35 U.S.C. § 112

In the final Office action dated April 20, 2007, the Examiner objected to the specification as failing to provide proper antecedent basis for the claimed subject matter with respect to the pressure range claimed in claim 1 of "between about 643 psig and about 2001 psig." Furthermore, the Examiner has rejected claims 1–10, and 23 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement because the claims "contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." In particular, the Examiner has asserted that the originally filed specification

does not provide support or antecedent basis for a claimed pressure range that was "between 643 psig and 2001 psig."

Pursuant to the conversation between the Examiner and attorneys for applicant Steven W. Hudnut and Peter E. Heuser during the May 24, 2007, telephone interview, applicant understands that the Examiner will withdraw the objection to a claimed pressure range of "between 643 psig and 2001 psig." In particular, the Examiner agreed that the specification, which discloses specific pressures of 643 psig, 1011 psig, 1030 psig, and 2001 psig adequately discloses a claimed pressure range of "between 643 psig and 2001 psig."

In addition, the Examiner has rejected claims 1–10, and 23 under 35 U.S.C. § 112, second paragraph, as being "indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." In particular, the Examiner stated that it "is unclear what applicant means by 'between about 643 psig and about 2001 psig.'" Applicant respectfully disagrees. With respect to the claim term "about" in claim 1, applicant respectfully asserts that, in light of the specification and the claim itself, one of ordinary skill in the art would understand what is claimed, as is required by MPEP § 2173.05(b). In particular, applicant respectfully asserts that one of ordinary skill in the art would recognize that the disclosed pressures, as with all measured physical quantities inherently include a degree of uncertainty. Thus, the claimed pressures of 643 psig and 2001 psig, which are respectively given to three and four significant figures, inherently include a reasonable range relative to the specific value. For example, applicant respectfully asserts that one of ordinary skill in the art would be unlikely to consider 2500 or 3000 psig to be "about 2001 psig." Thus,

for at least this reason, applicant respectfully requests that the rejections of claims 1–10, and 23 under 35 U.S.C. § 112 be withdrawn.

Rejections under 35 U.S.C. § 103

Claims 1–11, 13–17, 23, and 29 stand rejected under 35 U.S.C. § 103 as being unpatentable over Hauschild et al. (U.S. Pat. No. 6,905,475) in view of Glines et al. (U.S. Pat. No. 6,716,190). Applicant disagrees with the rejections, but has nonetheless made certain claim amendments to clarify what applicant regards as the invention.

Hauschild et al. is Not Available as a Reference for the Element "rigid"

As an initial matter, applicant respectfully asserts that amended claims 1–11, 13–17, 23, and 29 are fully supported under 35 U.S.C. § 112 by U.S. Patent Application Serial No. 10/085,564, of which the present application is a continuation-in-part, such that claims 1–11, 13–17, 23, and 29 have the effective filing date of that earlier parent application, as stated in the MPEP at § 706.02(V)(B). Furthermore, applicant respectfully asserts that claims 1–11, 13–17, 23, and 29, which are currently withdrawn, also have the effective filing date of that earlier patent application. Thus, the effective filing date for claims 1–11, 13–20, 23, and 27–31 is February 26, 2002.

Hauschild et al. issued from U.S. Patent Application Serial No. 10/269,405, which was filed on October 11, 2002. The 10/269,405 application claimed the benefit of U.S. Provisional Patent Application Serial No. 60/329,262, which was filed on October 12, 2001. As provided by the MPEP at § 2136.03(III), a U.S. patent that claims the benefit of a U.S. provisional patent application may NOT be applied as a reference under 35 U.S.C. § 102(e) as of the filing date of the provisional patent application unless the provisional application properly supports the subject matter relied upon to make the

rejection in compliance with 35 U.S.C. § 112, first paragraph. In making the rejections based on Hauschild et al., the Examiner has relied upon col. 4, lines 34–35, for the element "rigid." Applicant respectfully points out that this citation is to a paragraph in Hauschild et al. that was not included in or supported by the provisional application filed on October 12, 2001. In particular, the following paragraph from col. 4, lines 30–39, of Hauschild et al. was only included in the 10/269,405 application, which was filed on October 11, 2002:

> Notably, the present invention is suitable for use in two piece assemblies in contrast to the three piece assembly shown in FIG. 2. For example, the function of the sheath 26 and main body 31 could be combined into a unitary piece that is designed to operate in conjunction with endoscope 27. Also notably, the assembly may comprise a rigid assembly with, for example, a rigid sheath 26 and scope 27. Alternatively, the present invention includes embodiments that include flexible assemblies, including, for example, flexible scopes 27 and flexible sheaths 26.

Other than the above paragraph, Hauschild et al. contains no reference to "rigid" or "flexible." Thus, Hauschild et al. may only be relied upon for the element "rigid" as of October 11, 2002, which was the filing date of the 10/269,405 application.

As noted above, the effective filing date for claims 1–11, 13–20, 23, and 27–31 in the present application is February 26, 2002. This predates the critical reference date for Hauschild et al. Therefore, Hauschild et al. may not be cited against claims 1–11, 13–20, 23, and 27–31 to show the element "rigid."

Claim 1 and its Dependent Claims

As an initial matter, to the extent that Hauschild et al. might be available as a reference, Hauschild et al. teaches away from making the Examiner's proposed combination of Hauschild et al. with Glines et al. Thus, the proposed combination of Hauschild et al. with Glines et al. is improper.

The U.S. Supreme Court has recently reaffirmed the proposition that "when the

prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. ___, 82 USPQ2d 1385, 1395 (2007) (citing *United States v. Adams*, 383 U.S. 39, 51-52, 148 USPQ 479 (1966)). In particular, "known disadvantages in old devices which would naturally discourage the search for new inventions may be taken into account in determining obviousness." *Adams*, 383 U.S. at 52, 148 USPQ 479 (1966). Thus, showing "'that the art in any material respect taught away' from the claimed invention" can rebut a prima facie case of obviousness. *In re Geisler*, 116 F.3d 1465, 1469, 43 USPQ2d 1362, 1365 (Fed. Cir. 1997) (quoting *In re Malagari*, 499 F.2d 1297, 1303, 182 USPQ 549, 553 (CCPA 1974). "A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant . . . [or] if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant." *Tec Air, Inc. v. Denso Mfg. Mich. Inc.*, 192 F.3d 1353, 1360, 52 USPQ2d 1294, 1298 (Fed. Cir. 1999) (quoting *In re Gurley*, 27 F.3d 551, 553, 31 USPQ2D (BNA) 1130, 1131 (Fed. Cir. 1994)).

In the present Office action, the Examiner asserts that Hauschild et al. discloses ejecting fluid at "high pressure." In support of this assertion, the Examiner has cited col. 5, line 56 through col. 6, line 34. However, the cited section of Hauschild et al. offers no definition for "high pressure." Furthermore, as noted in the prior amendment, applicant respectfully asserts that Hauschild et al. does not disclose, teach, or suggest an ejection mechanism that is even capable of achieving the pressures claimed in claim 1 (between

about 643 psig and about 2001 psig). In particular, the surgical devices and kits disclosed in Figs. 4, 5, 9 and 10 and discussed at col. 6, line 35 through col. 7, line 27 of Hauschild et al. are all based on a standard hand-actuated syringe 86, as shown most clearly in Fig. 4. Hauschild et al. does not disclose, teach, or suggest any other source of ejection and/or injection pressure. As set forth in the Declaration of Keith K. Daellenbach, submitted with the prior amendment pursuant to 37 C.F.R. § 1.132, standard hand-actuated hypodermic syringes, such as the one illustrated at reference number 86 in Figs. 4, 5, 9 and 10 of U.S. Pat. No. 6,905,475 to Hauschild et al., are only capable of generating pressures that are significantly lower than the lower end of the needle-free pressure range of about 643 psig to about 2001 psig recited in amended claim 1. In particular, the upper end pressures achievable with hand actuated (i.e., with typical human hand strength) standard hypodermic syringes depend on the size of the syringe and range from 229 psig for a 3 mL hypodermic syringe to 98 psig for a 10 mL hypodermic syringe. Therefore, standard hypodermic syringes, the only source of ejection and/or injection pressure disclosed, taught or suggested in Hauschild et al., are not even capable of generating pressures anywhere near the pressure range of about 643 psig to about 2001 psig recited in amended claim 1. Accordingly, Hauschild et al. does not disclose, teach, or suggest an ejection mechanism adapted to eject the fluid from the fluid reservoir through the end effector and out of the injection orifice at a pressure between about 643 psig and about 2001 psig, as recited in amended claim 1.

Furthermore, Hauschild et al. discloses the need to limit pressures. In particular, at col. 6, line 35 to col. 7, line 28 (the section of Hauschild et al. immediately following the portion cited by the Examiner), Hauschild et al. discloses a pressure limiter and a

pressure indicator, which "prevent injection pressures from exceeding acceptable levels" to prevent "extravasation" (col. 6, lines 49–54). The pressure limiter "limit[s] injection pressures to predetermined or desired levels" (col. 6, lines 37–38) and the pressure indicator "indicate[s] when unacceptably high pressures have been reached" (col. 6, lines 39–40). Applicant respectfully points out that the need to "prevent injection pressures from exceeding acceptable levels" disclosed in Hauschild et al. is made in the context of pressure generating mechanisms (i.e., hand-actuated hypodermic syringes) that are not even capable of generating pressures within the pressure range recited in claim 1. Thus, in view of the need to limit even the significantly lower pressures generated by the hand-actuated syringes disclosed in Hauschild et al., Hauschild et al. teaches away from modifying the "high-pressure needle-less injection system" of Hauschild et al. to deliver or eject fluid at a pressure between about 643 psig and about 2001 psig, as recited in amended claim 1. Thus, the Examiner's proposed modification of Hauschild et al. to deliver or eject fluid at a pressure between 1800 and 2300 psi, as taught by Glines et al., is improper because Hauschild et al. teaches away from such a modification.

Amended claim 1 recites a needle-free jet injection device that includes, amongst other structure, an end effector that (1) is rigid, in that the end effector has "a longitudinal axis configured into a shape wherein the end effector is sufficiently rigid to maintain the shape of its longitudinal axis during use" and (2) has "at least one injection orifice [that] is oriented generally laterally to the longitudinal axis of the end effector."

As noted above, to the extent Hauschild et al. is available as a reference against claim 1, Hauschild et al. does not disclose, teach, or suggest a rigid end effector having

a longitudinal axis configured into a shape wherein the end effector is sufficiently rigid to maintain the shape of its longitudinal axis during use.

Furthermore, even if it could properly be combined with Hauschild et al., Glines et al. does not disclose, teach, or suggest a rigid end effector having a longitudinal axis configured into a shape wherein the end effector is sufficiently rigid to maintain the shape of its longitudinal axis during use and at least one injection orifice [that] is oriented generally laterally to the longitudinal axis of the end effector. As discussed previously during the prosecution of the present application, a "rigid" end effector is distinct from a "malleable and/or manipulatable" end effector, which may be adapted "to form around or within anatomical structures" during use, as discussed on page 12 of the specification of the present application. In particular, in a malleable and/or manipulatable end effector, the shape of the longitudinal axis may be manipulated during use such that the end effector may be steered or guided around or within anatomical structures during some laparoscopic, thoracoscopic, or arthroscopic procedures. In contrast to a malleable and/or manipulatable end effector, a rigid end effector, as recited in amended claim 1, is sufficiently rigid to maintain the shape of its longitudinal axis during use.

Rather, as shown in Figs. 12, 14a, and 14b, Glines et al. discloses a catheter for atraumatic delivery through the vasculature (col. 27, line 55). In contrast to a device that is sufficiently rigid to maintain the shape of its longitudinal axis during use, a catheter for atraumatic delivery through the vasculature must be steered or guided around or within anatomical structures during procedures, as is suggested or discussed in Figs. 14a and 14b and at col. 28, lines 34–35 of Glines et al. where the "catheter tip 420 has been delivered directly to within coronary artery 425."

For at least the reasons discussed above, the cited references, alone or in combination, do not disclose, teach or suggest a device as claimed in amended claim 1. Claims 2–10 and 23 contain further limitations that distinguish the cited references. Accordingly, amended claim 1 and its dependent claims patentably distinguish the cited art, and applicant respectfully requests that the rejections of claims 1–10 and 23 under 35 U.S.C. § 103 be withdrawn.

Claim 11 and its Dependent Claims

Amended claim 11 recites a needle-free jet injection device that, amongst other elements, includes a longitudinally rigid extension structure that (1) is sufficiently rigid to maintain a longitudinal shape during use and (2) includes a plurality of injection orifices provided in a sidewall of the distal region of the extension structure. As discussed above, to the extent Hauschild et al. is available as a reference against claim 11, neither Hauschild et al. nor Glines et al. discloses, teaches, or suggests a longitudinally rigid extension structure that is sufficiently rigid to maintain a longitudinal shape during use and includes a plurality of injection orifices provided in a sidewall of the distal region of the extension structure.

Thus, for at least the reasons discussed above, the cited references, alone or in combination, do not disclose, teach or suggest a device as claimed in amended claim 11. Claims 13–17 and 29 contain further limitations that distinguish the cited references. Accordingly, amended claim 11 and its dependent claims patentably distinguish the cited art, and applicant respectfully requests that the rejections of claims 11, 13–17, and 29 under 35 U.S.C. § 103 be withdrawn.

CONCLUSION

Applicant believes that this application is now in condition for allowance, in view of the above amendments and remarks. Accordingly, applicant respectfully requests that the Examiner issue a Notice of Allowability covering the pending claims. If the Examiner has any questions, or if a telephone interview would in any way advance prosecution of the application, please contact the undersigned attorney of record.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 11-1540.

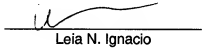
Respectfully submitted,

KOLISCH HARTWELL, P.C.

Steven W. Hudnut
Registration No. 57,786
Customer No. 23581
Attorney for Applicant
520 S.W. Yamhill Street, Suite 200
Portland, Oregon 97204
Telephone: (503) 224-6655
Facsimile: (503) 295-6679

CERTIFICATE OF E-FILING

I hereby certify that this correspondence is being transmitted electronically via the United States Patent and Trademark Office's EFS-Web System on June 19, 2007.



Leia N. Ignacio